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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,150	08/01/2005	Francis X. Smith	3009040 US01	6441

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/544,150	SMITH, FRANCIS X.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 11-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6 Aug 2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2009 has been entered.

Status of the Claims

2. Claims 1 and 9 have been amended. Claims 1-9 and 10-14 are presented for examination.

Information Disclosure Statement

3. The information disclosure statement filed 6 August 2009 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-4, 7-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee") in view of European Patent Application Publication EP0 734,732 (hereinafter "Tuyl").

Mowrey-McKee discloses contact lens disinfecting solutions comprising PHMB preservatives in concentrations ranging between 0.00001-0.1% by weight, 0.6-2% by weight tromethamine (C.1, L.45-52) to buffer the composition between pH 6-9 (C.2, L.16-24), preferably between pH 6.8-7.8 (C.2, L.60-62), citric acid as a chelating agent (C.2, L.36-52), surfactants including polyoxyethylenes (C.3, L.33-47), and additional agents including tonicity agents, surfactants, viscosity enhancing agents, and the like, including sodium chloride, potassium chloride, glycerol, or mixtures thereof. (C.3, L.21-32).

Mowrey-McKee does not specify that compounds such as thiamine, riboflavin, niacin, dexpanthenol, or pantothenic acid may be included.

Tuyl describes the use of riboflavin compounds, particularly vitamin B2, in contact lens disinfecting compositions where the riboflavin compound constitutes 0.075mg vitamin B2 in about 8 ml of fluid (a concentration of 0.93% w/v). (Claim 6).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have incorporated the riboflavin compound of Tuyl into the ophthalmic solution of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because both Mowrey-McKee and Tuyl describe solutions useful for treating ophthalmic conditions, and generally it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose, namely a composition for the treatment of ocular disorders. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

5. Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Tuyl as applied to claims 1-4, 7-9, and 11-14 above, and further in view of U.S. Patent 6,162,393 (hereinafter "De Bruiji").

Mowrey-McKee as modified by Tuyl describes an ophthalmic composition comprising riboflavin (Vitamin B2), as well as PHMB, preservatives, sequestering agents, and buffers adjusted to a pH of between 6.8-7.8, but does not specify the use of glycerin or decanedioic acid.

De Bruiji discloses the use of glycerin and decanedioic acid in ophthalmic compositions as described in the previous action.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the glycerin or decanedioic acid of De Bruiji with the contact lens disinfecting composition of Mowrey-McKee as modified by Tuyl. One having ordinary skill in the art would have been motivated to do so because glycerin or decanedioic acid because glycerin can reduce any minor toxic effects imparted to mammalian cells by a disinfectant and decanedioic acid increases the ocular comfort of contact lens solutions.

6. Claims 1-4, 7-9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,817,277 ("Mowrey-McKee") in view of British Patent Specification Publication GB 1,431,841 (hereinafter "Evans").

Mowrey-McKee discloses contact lens disinfecting solutions comprising PHMB preservatives in concentrations ranging between 0.00001-0.1% by weight, 0.6-2% by weight tromethamine (C.1, L.45-52) to buffer the composition between pH 6-9 (C.2, L.16-24), preferably between pH 6.8-7.8 (C.2, L.60-62), citric acid as a chelating agent (C.2, L.36-52), surfactants including polyoxyethylenes (C.3, L.33-47), and additional agents including tonicity agents, surfactants, viscosity enhancing agents, and the like, including sodium chloride, potassium chloride, glycerol, or mixtures thereof. (C.3, L.21-32).

Mowrey-McKee does not specify that compounds such as thiamine, riboflavin, niacin, dexpanthenol, or pantothenic acid may be included.

Evans describes an ophthalmic nutritional preparation for promoting the health of the eye and treatment of ophthalmic disorders. (Pg.1, L.9-25). These preparations contain a variety of vitamins, including thiamine, riboflavin, niacin, and pantothenic acid in a suitable form, including eye lotions or eye drops. (Pg.2, L.31-60). These compounds are to be included in amounts ranging from 0.5-20 milligrams. (Pg. 2, L. 40-60). Evans additionally indicates that ocular disorders may be treated by using "a multiple of the formula...which may be combined with additional quantities of additional nutrients." (Pg.2, L.1-3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time of the instant invention to have incorporated the nutritional preparation of Evans into the ophthalmic solution of Mowrey-McKee. One having ordinary skill in the art at the time of the instant invention would have been motivated to do so because both Mowrey-McKee and Evans describe solutions useful for treating ophthalmic conditions, and generally it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose, namely a composition for the treatment of ocular disorders. The idea for combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06.

Furthermore, given the general conditions of B-vitamin content described by Evans and Mowrey-McKee, it would have been obvious for a skilled artisan to arrive at the instantly claimed B-vitamin concentrations by the optimization of concentrations through routine experimentation. One having ordinary skill in the art would have been motivated to experiment with the B vitamin concentrations described by Evans and Mowrey-McKee because Evans specifically indicates that the quantities of vitamins, including the B vitamins therein described,

included for the treatment of ocular disorders may be adjusted according to the disorder being treated. Vitamin concentration is therefore recognized by the prior art as a result-effective variable, wherein the result being achieved is the effective treatment of a variety of ocular disorders.

Applicants arguments have been fully considered and are deemed unpersuasive. Applicants argue against the applicability of Evans in the instant invention by claiming that only multiple concentrations above those disclosed may be used to provide ophthalmic nutritional compositions in accordance with the invention of Evans. Applicants arguments fail for multiple reasons, including that the art teaches more flexibility than that advocated by applicants, as well as Applicants misinterpretation of the rejection as put forth by the examiner.

Applicants argue primarily that the quantities disclosed by Evans may be "multiplied to increase the dosage" of vitamins included in the ophthalmic composition therein described. (Request for Continued Examination, Page 6). The examiner asserts this statement misrepresents the intent of the invention disclosed by Evans, which requires only that the preparation "contain the following ingredients in the following ***relative quantities***." (Pg. 2, Lines 7-10). This places absolutely no upper or lower threshold on the quantities of vitamin B which may be incorporated into the ophthalmic composition by the skilled artisan. Furthermore, Evans suggests that strict adherence to the discrete numbers recited may not necessarily be required, as multiple ingredients are disclosed as capable of being included in approximations of the ratios disclosed. *See* Pg.2, L.77-99, (indicating some ingredients are modified to "say 30,000, 50,000, or 60,000 international units," "say 1 gram or 2 grams," "say 10mg, 15mg, 20mg," and, most interestingly, "the relationship of the remaining ingredients ***should*** however remain ***substantially*** as stated

above."). (emphasis added). This suggests to the skilled artisan that absolute quantities are not necessarily required, even acting to invite routine experimentation by the skilled artisan in producing ophthalmic compositions in the spirit of the invention therein disclosed.

It is this general disclosure of the suitability of certain nutrients as beneficial to the health of the eye which forms the heart of the examiner's rejection. Specifically, by simply disclosing the beneficial nature of certain vitamin additives to the health of the eye, Evans has established the general conditions which Applicants have claimed as their invention. With those conditions as a starting point, accompanied by the knowledge that a concentration of vitamin B in an ophthalmic composition provides benefits to the health of the eye, the skilled artisan is thereby capable of arriving at the instantly claimed concentrations through routine experimentation. MPEP § 2144.05(II). Applicants arguments to the contrary, seemingly requiring a direction, suggestion or motivation to arrive at the presently claimed vitamin B concentrations, echo the approach to obviousness admonished by the Supreme Court in *KSR International Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007). There the court specifically indicated that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." *Id.* at 1742.

Absent appropriate secondary indicia of nonobviousness connected to the invention as claimed and commensurate in scope therewith, the above rejection of record stands.

7. Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mowrey-McKee as modified by Evans as applied to claims 1-4, 7-9, and 11-14 above, and further in view of U.S. Patent 6,162,393 (hereinafter "De Bruiji").

Mowrey-McKee as modified by Evans describes an ophthalmic composition comprising thiamine, riboflavin, niacin, and pantothenic acid as well as PHMB, preservatives, sequestering agents, and buffers adjusted to a pH of between 6.8-7.8, but does not specify the use of glycerin or decanedioic acid.

De Bruiji discloses the use of glycerin and decanedioic acid in ophthalmic compositions as described in the previous action.

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to have combined the glycerin or decanedioic acid of De Bruiji with the topical ophthalmic composition of Mowrey-McKee as modified by Evans. One having ordinary skill in the art would have been motivated to do so because glycerin or decanedioic acid because glycerin can reduce any minor toxic effects imparted to mammalian cells by a disinfectant and decanedioic acid increases the ocular comfort of contact lens solutions.

Applicants arguments have been fully considered and are deemed unpersuasive for the reasons put forth in Paragraph 6, above.

Double Patenting

8. Claim 10 stands provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 11 of copending Application No. 11/620,318. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

9. Claims 1-9 and 11-14 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 11/620,318. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons put forth in the previous action. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Frederick Krass/
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